IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF NEW YORK

UNITED STATES OF AMERICA, *ex rel*. MICHAEL I. LEVINE, M.D., *Plaintiff-Relator,* v. ROBERT MATALON, M.D., JOSEPH SHAMS, M.D., DANIEL MATALON, M.D., AND ALBERT MATALON, M.D., *et al.,* *Defendants.*	)	Case No. 12-cv-05103-LGS

OMNIBUS OPPOSITION BY PLAINTIFF-RELATOR MICHAEL I. LEVINE, M.D. TO THE TWO SEPARATE MOTIONS TO DISMISS FILED BY DEFENDANT JOSEPH SHAMS, M.D., AND DEFENDANTS ROBERT MATALON, M.D., DANIEL MATALON, M.D., AND ALBERT MATALON, M.D.
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Plaintiff-Relator Michael I. Levine, M.D. ("Relator" or "Levine"), by his undersigned attorneys, respectfully submits this Omnibus Opposition to the twin Motions to Dismiss filed on October 24, 2019, by Defendant Joseph Shams, M.D. ("Shams"), Docket Entry Number ("Dkt. No. ") 180 ("Shams's MTD") and Defendants Robert Matalon, M.D., Daniel Matalon, M.D., and Albert Matalon, M.D. (the "Matalon Defendants"), Dkt. No. 176 ("Matalons' MTD").[1] All four defendants are collectively referred to as the "Defendants." Shams also filed his Memorandum of Law in Support of His Motion to Dismiss the Amended Complaint, Dkt. No. 181 (Shams's

[1] The Court allotted Levine twice the applicable page limit if he chose—as he does here—to file a single omnibus opposition to the two Motions to Dismiss filed by the various Defendants. See Order regarding full briefing of motions to dismiss, filed September 10, 2019, Dkt. No. 170.

Memo."); and the Matalons filed their Memorandum of Law in Support of Motion to Dismiss, Dkt. No. 178 ("Matalons' Memo."). Levine responds to the arguments contained in all four of these filings by the Defendants.

PROCEDURAL AND FACTUAL BACKGROUND

Levine filed this *qui tam* action on June 29, 2012. (Dkt. No. 1). The Government investigated Levine's complaint from that date through October 17, 2018, when the Government partially intervened, but declined to intervene in the claims against Shams and the Matalons (Dkt. No. 26). Levine his operative Amended Complaint ("Am. Compl.") on August 8, 2019 (Dkt. No. 163).[2] That complaint asserts two causes of action against the Defendants under the Federal False Claims Act ("FCA"). Count One alleges the Defendants knowingly presented, or caused to be presented, false or fraudulent claims in violation of 31 U.S.C. § 3729(a)(1). Count Two alleges the Defendants knowingly made, used, or caused to be made or used, false statements or records in violation of 31 U.S.C. § 3729(a)(2).[3]

[2] The Matalon Defendants attach a copy of the Amended Complaint (Dkt. No. 163) as Exhibit A to the Declaration of Brian L. Bank in support of their Motion to Dismiss. Levine subsequently on October 24, 2019 filed an Amended Complaint (Corrected), see Dkt. No. 184, which is identical in all material respects to the Amended Complaint and is the current operative complaint. Because these documents are materially identical, and for simplicity and the convenience of the Court and the parties, Levine envisions no need to attach Dkt. No. 184 to a declaration of counsel in support of this Opposition, and instead refers to the version (Dkt. No. 163) attached to Mr. Bank's Declaration.

[3] The Amended Complaint uses the pre-2009 designation of these two liability provisions of the FCA, *i.e.*, 31 U.S.C. § 3729(a)(1) (false claims) and (a)(2) (false statements to get false claims paid or approved); pursuant to the Fraud Enforcement and Recovery Act Of 2009 ("FERA"), Pub. L. Pub. L. 111–21, § 4(a), 123 Stat. 1621 (May 20, 2009), these respective sections were re-designated as, respectively, 31 U.S.C.. §§ 3729(a)(1)(A) and (a)(1)(B).

ARGUMENT

I. LEVINE'S CLAIMS ARE TIMELY AND THE COURT SHOULD THEREFORE DENY SHAMS'S MTD ON STATUTE OF LIMITATIONS GROUNDS

Shams (but not the Matalons) contends Levine's Amended Complaint should be dismissed as untimely because it "does not allege any purportedly false or fraudulent action by Shams after some unspecified point in 2009," which means, "at the absolute latest, the [FCA's six-year statute of] limitations period expired in 2015." Because the current complaint was filed on August 5, 2019, Shams contends it must be dismissed in its entirety. Shams's Memo. at 22-23. Shams is incorrect and his MTD on this ground should be denied.

First, Shams is factually wrong that the Amended Complaint does not allege false claims after 2009. In ¶¶ 95-110, Levine alleges that Shams submitted false claims on Forms 1500 and/or Form 1450 for medically unnecessary "balloon dilations of narrowed or blocked vein," HCPCT Code 35476 (which is pleaded as an example of unnecessary vascular access procedures for which Shams billed), from 2012 through 2017. The false claims between August 6, 2013 and 2017 manifestly are timely under the FCA statute of limitations because they were submitted within six years of the date on which the Amended Complaint was filed; they therefore are not subject to dismissal on this ground.

Second, Levine can recover for false Medicare claims submitted by Shams after June 29, 2006, which is six years back from the date when Levine filed his original complaint on the theory that his filing tolled the running of the six-year FCA statute of limitations. Thus, each and every false Medicare claim that Shams submitted on or after June 30, 2006 would have been within the statute of limitations running back six years from his original complaint filed June 29, 2012.

Under Fed.R.Civ.P. 3, the filing of a complaint commences an action and tolls the applicable statute of limitations. *U.S. ex rel. Costa v. Baker & Taylor, Inc.*, 1998 U.S. Dist. LEXIS 23509 (N.D. Cal. Mar. 20, 1998), *9. With respect to the timeliness of a relator's own claims in which the Government declines to intervene, the six year statute of limitations runs backward from the date when the relator first filed her complaint. *Hayes v. Dept. of Educ. of City of New York,* 20 F. Supp. 3d 438, 449 (S.D.N.Y. 2014) ("*Hayes"*).[4]

The fact that the claims in Levine's own original complaint remained under seal at the Government's request, and based on the Court's orders (see Dkt. Nos. 2-25), does not affect the fact that the statute of limitations was tolled as to Levine's own claims. As the Court explained in *Hayes*:

> Distinguishing between the relevant tolling date for a relator and for the Government is a sensible application of the structure of the FCA itself. A relator may commence a qui tam action unilaterally, 31 U.S.C. § 3730(b)(1), but after the action is brought cannot influence when the complaint is ultimately unsealed, id. § 3730(b)(3). . . . There is no valid reason to punish an otherwise diligent relator by stripping away claims when the Government, not the relator, is to blame for preventing the defendant from receiving notice of the action against it. *See, e.g., United States ex rel. Parikh v. Premra Blue Cross,* No. 01 Civ. 0476 (MJP), 2007 U.S. Dist. LEXIS 24845, 2007 WL 1031724, at *3 (W.D. Wash. Apr. 3, 2007) ("It would also be unfair to penalize relators by barring their claims on timeliness grounds when they cannot control a court's decision to permit multiple extensions of the seal."). The statute of limitations for any claim pleaded in Plaintiff's original complaint was tolled when she filed that complaint.

[4] It is the **filing** of a relator's complaint, not its subsequent **unsealing**, that halts the running of the statute of limitations as to the relator's claims. *Miller v. Holzmann*, 2006 U.S. Dist. LEXIS 9165, 2006 WL 568722, at *5 (D.D.C. 2006) ("Unfortunately for the defendants, the contention that the statute of limitations is not tolled until the unsealing of the relator's complaint has been rejected by every court in which it has been made.") (citing *In re Cardiac Devices Qui Tam Litigation*, 221 F.R.D. 318, 357-58 (D. Conn. 2004); *U.S. ex rel. Downy v. Corning, Inc.,* 118 F. Supp. 2d 1160 (D.N.M. 2000), overruled on other grounds, *U.S. ex rel. Sikkenga v. Regence Bluecross Blueshield of Utah,* 472 F.3d 702 (10th Cir. 2006)).

Hayes at 444-445.

Consequently, Levine's original June 29, 2012 complaint properly encompasses all false claims submitted by Shams to Medicare on or after June 30, 2006, and at all times thereafter. And this is so, regardless of whether the Amended Complaint relates back to the original complaint.

Shams relies heavily on *U.S. v. Baylor Univ. Med. Ctr.*, 469 F.3d 263 (2d Cir. 2006) in arguing that Levine's claims in the Amended Complaint cannot relate back to the claims against Shams in Levine's original complaint. This reliance on *Baylor* is misplaced. The holding of *Baylor* was that claims brought by the Government in an amended complaint in intervention do not relate back to the relator's original complaint. *See id.* at 269 ("We disagree, and hold that--in light of the scheme created by 31 U.S.C. § 3730(b)--Rule 15(c)(2) does not allow complaints-in-intervention filed by the government to relate back to a relator's qui tam complaint.). The United States declined all of Levine's claims as to Shams (and the Matalons). Therefore, *Baylor* is not controlling. To the contrary, tolling applies, and renders any and all false claims submitted by Shams subsequent to June 29, 2006 timely under the FCA. *Hayes* at 449.

Relation back applies under Fed.R.Civ.P. 15(c)(1)(B) so long as the amended complaint "asserts a claim . . . that arose out of the conduct, transaction, or occurrence set out—or attempted to be set out—in the original pleading." Here, Levine's Counts One and Two in his August 5, 2019 pleading assert claims against Shams which he set out, or attempted to set out, in his June 28, 2012 original complaint.

In that original complaint, Levine charged Shams, among other physicians, with performing medically unnecessary access center procedures on patients (Dkt. No. 1, p. 16,

heading I, and ¶¶ 66-79; heading (B) at p. 19 and ¶¶ 80-88, and ¶ 97.) The Amended Complaint alleges the same scheme and conduct on Shams's part, albeit with further particulars. Fleshing out the original claim with more particulars should not be held to vitiate relation back under Fed.R.Civ.P. 15(c)(1)(B) since Levine did so only to cure Defendants' contentions that he had not pleaded fraud with particularity required to meet Rule 9(b) in the first place (see Dkt. Nos. 132 and 134), and this Court expressly adjourned Levine's response to those arguments to allow him to amend his complaint to cure those alleged defects. (Dkt. No. 159.) Levine did so in Dkt. 163, and that document should be held to relate back to his original complaint.

Nothing in the *Baylor* decision precludes a relation back holding in this case since, as explained above, *Baylor* merely held that an amended complained filed by the Government cannot relate back to a relator's original complaint, and says nothing about whether an amended complaint by the relator can do so. This Court's decision in *Hayes*, moreover, expressly declined to hold a relator responsible for the fact that defendants did not receive immediate notice of the relator's filing of the lawsuit when the delay was the result of the Government's unilateral decision to seek numerous extensions of the seal during its investigation. The logic flowing from *Baylor* and *Hayes* is that Levine's claims herein relate back to his original complaint, even though the Government's do not.

In summary, based both on tolling and relation back, the Amended Complaint is not subject to dismissal on statute of limitations grounds, and the Court should deny this portion of Shams's MTD.[5]

[5] Moreover, even if some of Levine's claims were barred by the six-year FCA limitation, those predating August 5, 2019 by up to six years, would still be timely. The idea that all claims

II. LEVINE'S AMENDED COMPLAINT STATES LEGALLY SUFFICIENT CAUSES OF ACTION AGAINST SHAMS PURSUANT TO THE FALSE CLAIMS ACT, 31 U.S.C. § 3729, AND, THEREFORE, SHAMS's MTD SHOULD BE DENIED.

Levine's Amended Complaint (Dkt. No. 163) states proper and sufficient claims against Shams under the False Claims Act, 31 U.S.C. § 3729 (FCA). Count One is pleaded under 31 U.S.C. § 3729(a)(1) for the knowing presentment of a false or fraudulent claim; and Count Two is laid under 31 U.S.C. § 3729(a)(2) for the knowing making, using, or causing to be made or used records or statements material to false or fraudulent claims. These claims as pled meet the standards applicable under Federal Rules of Civil Procedure 12(b)(6) and 9(b).

A. Legal Standard

As this Court explained in *Cohen v. Kitov Pharm. Holdings, Ltd.*, 17 Civ. 0917 (LGS), 2018 WL 1406619, at *3 (S.D.N.Y. Mar. 20, 2018), to survive a motion to dismiss under Rule 12(b)(6), "a complaint must contain sufficient factual matter, accepted as true, to 'state a claim to relief that is plausible on its face.' " *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (quoting *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007)). "A claim has facial plausibility when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the

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in a complaint must be dismissed because some are untimely, has never been the law this Circuit. *See Shah v. New York State Dept. of Civ. Serv.*, 168 F.3d 610, 612–13 (2d Cir. 1999) (upholding the District Court's dismissal of seven Title VII employment discrimination claims on statute of limitations grounds, but reversing, vacating, and remanding the lower court's dismissal of two other Title VII claims as untimely, concluding that they were not barred by the statute of limitations and that the case should therefore go forward); *Murphy v. Lynn,* 53 F.3d 547, 547 (2d Cir. 1995) ("On the eve of trial, the District Court ruled that Murphy's action was precluded by the statute of limitations. It is now clear that, though some of his causes of action were properly dismissed as time barred, not all of Murphy's claims were untimely. We therefore reverse and remand for further proceedings. … Consequently, the District Court's complete dismissal of Murphy's action as time barred was erroneous and cannot stand.").

defendant is liable for the misconduct alleged." *Id.* (citing *Twombly*, 550 U.S. at 556). It is not enough for a plaintiff to allege facts that are consistent with liability; the complaint must "nudge[ ]" claims "across the line from conceivable to plausible." *Twombly*, 550 U.S. at 570. "To survive dismissal, the plaintiff must provide the grounds upon which his claim rests through factual allegations sufficient 'to raise a right to relief above the speculative level.' " *ATSI Commc'ns, Inc. v. Shaar Fund, Ltd.*, 493 F.3d 87, 98 (2d Cir. 2007) (quoting *Twombly*, 550 U.S. at 555). On a Rule 12(b)(6) motion, "all factual allegations in the complaint are accepted as true and all inferences are drawn in the plaintiff's favor." *Apotex Inc. v. Acorda Therapeutics, Inc.*, 823 F.3d 51, 59 (2d Cir. 2016).

B. The Amended Complaint States a Legally Sufficient Cause of Action Against Shams for Presenting False or Fraudulent Claims in Violation of 31 U.S.C. §3729(a)(1).

1. The Elements of a Claim under 31 U.S.C. §3729(a)(1).

The five elements of a claim under 31 U.S.C. §3729(a)(1) are that the defendant: (1) made claims; (2) to the United States; (3) that were false or fraudulent;(4) knowing the claims were false or fraudulent; and (5) which claims sought payment from the treasury. *See, e.g., U.S. ex rel. Kolchinsky v. Moody's Corp.*, 238 F.Supp. 3d 550, 556-557 (S.D.N.Y. 2017). The Amended Complaint in this case clearly pleads all five elements and, therefore, states a legally sufficient claim.

2. The Factual Allegations of the Amended Complaint vis-à-vis the Elements of 31 U.S.C. §3729(a)(1).

a. Elements 1, 2, and 5: Shams made false claims to the United States which sought payment from the Treasury.

The Amended Complaint pleads elements 1, 2, and 5 against Shams in paragraphs ¶ 95 ("Shams … billed for these unnecessary visits and procedures using Forms 1450 and/or Forms

1500.") and ¶ 29 ("Defendants also received payments from Medicare."). The complaint alleges that Medicare is a program funded by the United States, and it therefore follows necessarily that Shams' claims for Medicare payments were made to the United States. Paragraph 6 alleges:

> The violations of the False Claims Act arose because Defendants (as described more fully below) have submitted, and/or caused to be submitted, false and fraudulent claims, … and in payment thereof received funds from Medicare and Medicaid … .

In summary, ¶¶ 1, 5, 6, 29, 30, 139 and 145 properly plead that the United States funds the payments Medicare made to Shams, and that, in making claims under Medicare, Shams presented claims to the United States.

In *U.S. ex rel. Mikes v. Straus*, 274 F.3d 687, 695-96 (2nd Cir. 2001), the court held that each submission of the HCFA-1500 form meets the first two elements of a False Claims Act cause of action in that it qualifies as a claim made to the United States government. *See U.S. v. Krizek*, 111 F.3d 934, 940 (D.C. Cir. 1997) (holding that number of claims under Act based upon submission of HCFA-1500 forms).

b. Element 3: The Amended Complaint pleads the false and fraudulent scheme with the requisite particularity under Rule 9(b).

Levine's complaint pleads a solid cause of action against Shams for submitting false claims in violation of 31 USC § 3729(a)(1), now § 3729(a)(1)(A), and does so by setting forth "the circumstances constituting fraud" with the requisite particularity required by Rule 9(b) of the Fed.R.Civ.P., as applied by the Second Circuit in *U.S. ex rel. Chorches v. American Medical Response, Inc.*, 865 F. 3d 71, 83-84 (2d Cir. 2017). The Amended Complaint pleads specific facts supporting a strong inference of fraud by Shams. *Id.*

The fraudulent scheme consisted in performing medically unnecessary vascular access procedures and billing Medicare and Medicaid for them. Medical necessity is a fundamental

requirement for the United States to reimburse a cost under Medicare. (Amended Complaint, ¶¶ 47 and 48.)

Medicare does not cover any expenses incurred for services that "are not reasonable and necessary for the diagnosis or treatment of illness or injury . . . ." 42 U.S.C. § 1395y(a)(1)(A); 42 U.S.C. § 1320c-5(a). To be covered, the expense must be supported by "evidence of medical necessity" in the patient's file. 42 U.S.C. § 1320c-5(a). (*Id.*, ¶ 48.) Importantly, diagnostic tests "must be ordered by the physician who is treating the beneficiary," and only by the patient's treating physician, that is, solely by

> the physician who furnishes a consultation or treats a beneficiary for a specific medical problem and who uses the results in the management of the beneficiary's specific medical problem. Tests not ordered by the physician who is treating the beneficiary are not reasonable and necessary."

42 C.F.R. § 410.32. (*Id.,* ¶ 49.)

The fraudulent scheme is set forth in ¶¶ 71-72:

> Shams followed practice of "holding on to" or "capturing" patients for continual monitoring and treatment of their vascular accesses, instead of sending them back to their treading nephrologists and dialysis units to determine whether prior procedures were successful and for further surveillance, as he was required to do by Medicare and Medicaid requirements.

The Complaint pleads the nature and effectuation of this scheme in detail.

Levine recognized that Shams was perpetrating this scheme based on his long experience and observations working in this field. Levine had the vantage point of having seen vascular access procedures done wrong by Dr. McGuckin. ¶ 74-79. He had the vantage of seeing them done right by the interventionists, including himself, when he worked in Milwaukee. ¶¶ 80-81. Levine had a conversation with the Medical Director of American Access Care, who told Levine

he routinely scheduled patients he had treated for a certain kind of malfunction for unnecessary follow-up procedures, a practice Levine knew was unlawful. ¶90.

With Levine's wealth of perspective, he became aware that Shams and other Beth Israel radiologists engaged in a practice of "self-referral" identical to that of Dr. James McGuckin ("McGuckin") and his clinics. Multiple times Levine was informed by patients he cared for while employed by Dr. Robert Matalon that the patients were to return for follow-up appointments for access evaluations even though neither Levine, nor any of the other healthcare professionals in the dialysis units, initiated the referrals. (Amended Complaint, ¶85.)

One example was Patient RG, who, about the summer of 2009, experienced access thrombosis and was referred to Beth Israel for access declotting, also known as a percutaneous thrombectomy. Often when a dialysis patient experiences thrombosis, the underlying problem is a flow-limiting narrowing(s) in the access system, which requires angioplasty in order for the thrombectomy to be successful and have a durable outcome. In RG's case, the procedure was performed successfully and the access appeared by allavailable measures to be functioning adequately, and therefore at the time Levine saw the patient there was no reason for a repeat fistulagram. RG nonetheless was scheduled for a follow-up visit to the Beth Israel Union Square Radiology Center. Levine, after evaluating RG's access, recommended that RG did not need to return for the two week follow-up appointment that the Union Square Center had arranged following the successful thrombectomy. (Amended Complaint, ¶ 86.)

Shams argues that the Amended Complaint does not charge him with having performed the initial procedure or scheduling the "routine" follow-up procedure involving RG. (Shams's Memo. at 5.) The Amended Complaint does, however, recount Levine's personal conversation directly with Shams in which Shams admitted that Beth Israel engaged in a routine and regular

practice of automatically scheduling patients on whom its physicians had worked for follow-ups even after successful procedures. (Amended Complaint, ¶¶ 87-91.) It was the content of Shams's admission, which is recounted in the Amended Complaint with specificity, which led Levine to conclude that Shams (and perhaps other Beth Israel) physicians were performing unnecessary procedures billed to Medicare, and thereby engaging in a fraud scheme.

According to the Amended Complaint, Shams admitted that it was Beth Israel's a routine practice to schedule patients for a two week follow-up following angioplasty associated with a percutaneous thrombectomy, and that "everyone did it" including American Access Care. (Amended Complaint, ¶ 87.) Shams clearly conceded through this statement to Levine that he, Shams, was one of the Beth Israel physicians who followed this practice. That made sense to Levine, who knows, based on his personal experience in the field, that all the interventionists in a given practice follow the same corporate-wide practices and policies as far as routine follow-ups were concerned. (Amended Complaint, ¶¶ 80-83.)

In this same conversation, which obviously occurred with a short time of Levine seeing RG—contrary to Shams's complaining that the date of the conversation is not alleged in the Amended Complaint (Shams's Memo. at 5)—Shams asserted a pretextual medical reason to Levine for his and Beth Israel's routine practice. Shams told Levine that Beth Israel had found a high incidence of clinically significant restenosis two weeks post-declotting. Levine challenged Shams to publish this finding because it was contrary to the published medical literature. Shams never did. (Amended Complaint, ¶ 88.)

Shams stated to Levine that RG did not have to return, if Levine did not think it was medically necessary. Shams wrongly asserts this is exculpatory "because another physician,

Levine, determined the procedure a success." (Shams's Memo. at 5.) The fact is that, in this instance, Shams got caught.

As the Amended Complaint states, the way in which the system is supposed to operate is that the interventionist (Shams) is always supposed to send the patient on which he or she performs a procedure back to the treating nephrologist to ascertain whether that procedure was a success or not, and is not to perform any routine follow-up examinations or procedures unless the treating nephrologist refers the patient again. (Amended Complaint, ¶¶ 55-64 and 68-70.)

Thus, Shams could not be legitimately reimbursed by Medicare for procedures such as fistulagrams and angioplasties in the absence of a referral by a patient's treating nephrologist, based on the necessity for such a procedure (as documented by the treating doctor in the patient's chart), and was not permitted to "self-schedule" patient follow-up visits without a new referral from the treating physician.

Stated another way, only the nephrologist/dialysis unit were to monitor patient's vascular access on a continual basis under Medicare in exchange for capitation payments. ¶¶ 36-37, 46, 50. They were in best position to do so. ¶¶ 54-57. Consequently, Shams and the access center were not authorized to perform that task. ¶ 55. Medicare Local Coverage Determinations ("LCDs") provided that Medicare would not pay for services, including angiograms that are only screening or evaluative in nature. ¶61.

Under Medicare's reimbursement rules, the role of physicians such as Shams working in the vascular access center, was limited to doing two things: (a) after referral from and express authorization by a nephrologist or dialysis center, creating a long term vascular access; and (b) after referral from and express authorization and approval by a nephrologist or dialysis unit, performing an angiogram or corrective procedure. ¶ 67. Shams had no need, justification, or

authority to monitor patients after completion of the corrective procedure, at least not for Medicare purposes. ¶¶ 69-70. Shams's practice violated applicable Medicare LCDs, which required, among other things, that for an access procedure to be payable under Medicare as reasonable and necessary, the patient's nephrologist must have determined (based on the patient's clinical record)that the procedure was clinically indicated. Amended Complaint, ¶¶ 58-63.

Shams's self-scheduled vascular access procedures therefore were medically unnecessary, unreasonable, and illegitimate and his submission of claims for payment under Medicare for those procedures, including, for example, the procedure denominated by HCPCT Code 35476, "balloon dilation of narrowed or blocked vein," constituted false or fraudulent claims in violation of 31 U.S.C. § 3729(a)(1). *See* Amended Complaint, ¶¶ 104-110, and 140.

Levine's misgivings were heightened further still when Shams stated that among the "everyone[s]" who engaged in this unlawful practice was "American Access Care." Id., ¶¶ 87, 91. Among the vascular access centers operated by Dr. McGuckin, whom Levine had reason to believe was committing a similar fraud, were some titled "American Access Care of PA LLC" and "American Access Care of South Philadelphia." Am. Complaint, ¶ 21. Thus, "Shams' statement to justify his routine scheduling of Patient RG for follow-up medical appointments because 'everyone did it' including American Access Care bolstered Dr. Levine's conclusion that Shams engaged in these unnecessary and illegal practices as a matter of course." Id., ¶ 91.

Levine's Amended Complaint contains other particularized cases in addition to that of RG. In about June 2011, Dr. Levine treated Patient JO. JO experienced access thrombosis, and also was referred to Beth Israel for declotting. This procedure was successful. Yet, Dr. Levine learned that JO also had been scheduled for a two week follow-up visit to Beth Israel's access

clinic. Dr. Levine recommended that JO not return unless and until there were clinical indications that JO was experiencing further complications with his/her access. (Amended Complaint, ¶ 92.) Even if it was not Shams himself who individually self-scheduled JO for routine follow-ups, the case of JO reinforces that this was Beth Israel's corporate practice and policy, which Shams personally applied, as revealed by his admission to Levine re RG, and the frequency with which he performed balloon angioplasties on each of his patients, as alleged in ¶¶ 104-110 of the Amended Complaint.

There is also the particular case of Patient MH. As detailed at ¶¶ 93-94:

> Dr. Levine was the primary nephrologist for Patient MH. MH was undergoing dialysis at the Beth Israel Dialysis Unit at Irving Place in Manhattan. MH had undergone an access procedure in February 2011 (prior to Dr. Levine assuming the role as his/her primary nephrologist) because, at that time, MH's access flow was depressed. It was restored to its baseline following the procedure.
>
> Following that successful procedure, MH underwent multiple repeat procedures at Beth Israel Union Square Center, even though his/her access was performing well based on overt clinical parameters as well as having stable intra-access blood flows, the latter being the most accurate and objective measure of access function, according to many experts in the field. MH explained to Dr. Levine that she/he went repeatedly to Beth Israel because they told him/her to do so, and because she/he was afraid if she/he did not go, something bad would happen to him/her. Dr. Levine had not initiated these referrals and Dr. Levine was not aware of any other medical professional initiating the referrals of MH for repeat visits to Beth Israel. That is so, notwithstanding a report indicating that a Dr. Steven Haveson was the referring surgeon. Dr. Levine, based on his course of treatment of MH, believed Dr. Haveson was not treating MH at the time the record said the latter had referred MH to Beth Israel. Furthermore, Dr. Levine is aware that MH has had significant allergic reactions to the administered x-ray contrast fluid on occasions when she received repeat angiograms at Beth Israel.

These allegations meet the requirement of Rule 9(b) as the Second Circuit applied it in *Chorches*.

c. Element 4: An FCA Complaint May Allege Scienter Generally

"Scienter may be pled generally under both the FCA and Rule 9(b). *See Gold [v. Morrison Knudsen Co.]*, 68 F.3d [1475], 1477 (noting that the FCA's liberal scienter requirement is consistent with Rule 9(b)); 31 U.S.C. § 3729(b) ("no proof of specific intent to defraud is required"); FED. R. CIV. P. 9(b) ("Malice, intent, knowledge, and other condition of mind of a person may be averred generally.")." *U.S. ex rel. Smith v. Yale University*, 415 F. Supp. 2d 58, 83 (D. Conn. 2006). Levine has pleaded scienter sufficiently. (Amended Complaint, ¶¶ 6, 139-140.)

3. The Factual Allegations Meet the Requirements of Rule 9(b) as Applied by the Second Circuit in its *Chorches* Decision

In *Chorches*, the Court of Appeals unanimously reversed two lower decisions that had dismissed FCA claims on Rule 9(b) grounds, holding that the lower courts had unjustifiably applied rigid, inflexible, and overly "'strict[]'" tests in assessing whether FCA claims satisfy Rule 9(b) requirements. *Chorches*, 865 F.3d at 92, n.21. Indeed, the Court of Appeals went out of it way to lament that "district courts in this Circuit that have confronted this issue have tended to apply [a] 'stricter' pleading standard" to FCA claims than is warranted by the text or legislative purposes behind the Rule or the FCA. *Id.* Without expressly overturning any Second Circuit decisions, *Chorches* still stressed that its decision to reverse the lower court rulings "is clearly consistent with the approach taken by the Third, Fifth, Seventh, Ninth, Tenth, and D.C. Circuits, which have overtly adopted a 'more lenient' pleading standard." 865 F.3d at 90 (emphasis added).

The *Chorches* Court began by emphasizing what the Defendants conveniently ignore: the obligation of courts reviewing Rule 12(b)(6) motions to "'accept[] all factual allegations as true and draw[] all reasonable inferences in favor of the plaintiff.'" *Chorches,* 865 F.3d at 78

(citations omitted). Thus, even under the heightened pleading standards established by *Bell Atl. Corp. v. Twombly*, 550 U.S. 544 (2007), and *Ashcroft v. Iqbal*, 556 U.S. 662 (2009), for Rule 12(b)(6) motions, a complaint need not prove a plaintiff is likely to prevail. Instead, a complaint need only "plead 'enough facts to state a claim to relief that is plausible on its face,'" and enough facts to "'allow[ ] the court to draw the reasonable inference that the defendant is liable for the misconduct alleged.'" *Chorches*, 865 F.3d at 78 (citations omitted).

Of equal importance, the Court of Appeals admonished lower courts to "remember[] what Rule 9(b) actually requires" and not to conflate Rule 9(b)'s comparatively modest "require[ments]" with the more stringent conditions imposed by other Congressional enactments. *Chorches*, 865 F.3d at 88. To be sure, Rule 9(b) "demands specificity, but unlike such substantive reforms as the Private Securities Litigation Reform Act of 1995 ('PSLRA'), it does not elevate the standard of certainty that a pleading must attain beyond the ordinary level of plausibility." *Id*. (footnote omitted; emphasis added).

"Nor does [Rule 9(b)] forbid pleading upon information and belief where, as here, "facts are peculiarly within the opposing party's knowledge." *Id.* at 81-82. "Pleading on information and belief is a desirable and essential expedient when matters necessary to complete the statement of a claim aree not within the knowledge of the plaintiff, but he has sufficient data to justify interposing an allegation on the subject." *Id.* at 82. The complaint there passed muster under Rule 9(b), even though the relator "concede[d] he [could not] identify exact billing numbers, dates, or amounts for claims submitted to the government." *Id. Chorches*at 82.

Chorches explained, however, that that "conce[ssion]" was not fatallargely because the amended complaint "establish[ed] specific reasons why such information regarding the particular bills that were submitted for reimbursement [wa]s peculiarly within [the defendant's]

knowledge." *Id.* Other courts have held as few as three examples may suffice to satisfy Rule 9(b). Here, Levine has pled four exemplar cases involving Patients RG (Amended Complaint ¶¶ 86-89), JO (id., ¶ 92) , MH (id., ¶¶ 93-94), and CB (id., ¶ CB).

Levine has provided similar "reasons" why he cannot identify exact billing numbers, dates, or amounts for claims the Defendants submitted to Medicaid and Medicare for reimbursement. *See, e.g.,* Am. Compl. ¶ 95 (Levine lacks access to the Defendants' billing departments and personnel and "[c]onsequently, specific knowledge regarding these false claims is peculiarly within the knowledge of Defendants."). *See Chorches*, 865 F.3d at 82. Contrary to Shams' and the Matalon Defendants' contentions, "Rule 9(b) requires nothing more," *Chorches,* 865 F.3d at 89.

Moreover, as in *Chorches*, the Amended Complaint is "not merely general or conclusory" but, instead "alleges a basis for a strong inference that specific false claims were indeed submitted to the Government." *Chorches*, 865 F.3d at 83. The Amended Complaint provides ample specific and plausible facts (all of which must be taken as true) from which the Court may readily infer that the Defendants committed fraud by submitting false claims implicitly representing that follow-up fistulagrams and similar procedures were medically necessary and thus reimbursable by the government. In addition, by alleging with particularity the Defendants' scheme to falsify the medical necessity of follow-up fistulagrams and similar procedures, and by "identifying particular cases in which [that] fraudulent scheme was carried out, [Dr. Levine] has 'overcome the bar erected by Rule 9(b) to spurious charges or frivolous lawsuits.'" *Chorches*, 865 F.3d at 87 (citations omitted).

In summary, Levine's allegations against Shams plead "plausible and particularized allegations" of false and fraudulent claims submitted in violation of the FCA.

C. The Amended Complaint States a Legally Sufficient Cause of Action Against Shams for Making, Using, or Causing to be Made or Used False Records or Statements Material to a False or Fraudulent Claim in Violation of 31 U.S.C. § 3729(a)(2).

The Amended Complaint also satisfies the elements for pleading a valid claim under 31 U.S.C. § 3729(a)(2), making false statements material to a false or fraudulent claim and does so with a sufficient level of particularity, as required under *Chorches*. Therefore, Shams's motion to dismiss Count Two should be denied.

First, the fraudulent scheme Levine pleaded in Amended Complaint under §3729(a)(2) is that same as the scheme described above in satisfying Levine's case for his § 3729(a)(1) claim. As explained above, that scheme is alleged with particularity as required by Rule 9(b).

Second, Shams's false statements for §3729(a)(2) purposes are the certifications on the Forms 1500 he submitted to the Medicare program in claiming Federal reimbursement. *See U.S. ex rel. Groat v. Boston Heart Diagnostics Corp.*, 255 F. Supp. 3d 13, 18 (D.D.C. 2017) ("The CMS-1500 form requires the entity to certify that, among other things, 'the services on this form were medically necessary."); *U.S. ex rel. Smith v. Yale University*, 415 F. Supp. 2d at 63-64 ("[T]he form that physicians must submit to Medicare and Medicaid in order to be entitled to reimbursement [referring to CMS Form 1500] includes the following certification: 'Signature of Physician or Supplier: I certify that the services shown on this form were medically indicated and necessary for the health of the patient and were personally furnished by me or were furnished incident to my professional service by my employee under my immediate personal supervision."). Shams' made knowing false statements when he certified on the Forms 1500 he signed that procedures he performed—which, in fact, were medically unnecessary—met the requirement of medical necessity.

Shams's certifications of medical necessity were **material** to his claims for Medicare reimbursement as interpreted by the Supreme Court in *Universal Health Servs., Inc. v. U.S. ex rel. Escobar,* 136 S. Ct. 989 (2016) because medical necessity is a condition of the payment of a Medicare claim pursuant to 42 U.S.C. § 1395y(a)(1)(A) and other statutes. (Amended Complaint, ¶¶ 47-49.)

Accordingly, Count Two adequately pleads a proper claim against Shams for submitting false statements material to fraudulent and false claims in violation of 31 U.S.C. § 3729(a)(2).

III. THE COURT SHOULD DENY SHAMS'S FED.R.CIV.P. 12(b)(1) MOTION ASSERTING LACK OF SUBJECT MATTER JURISDICTION BASED ON THE FCA'S PUBLIC DISCLOSURE-ORIGINAL SOURCE PROVISION

Shams (but not the Matalons) contends that this Court lacks subject matter jurisdiction over Levine's action because Levine based his allegations vis-à-vis Shams exclusively on publicly disclosed information as to which Levine is not the original source. Shams's Memo. at 12-14. Shams is wrong for several reasons, and his effort to dismiss the Amended Complaint on this ground should be denied.

First, it is manifest from the foregoing review of the Amended Complaint that Levine bases his substantive allegations on his own personal experiences, observations, and conversations, not on public disclosures (see, e.g., ¶¶ 10, 14, 78-80, 82, 87-88, 90, 94, 95, 110, 115, 121, and others discussed above).

Second, Shams relies on an outdated version of the public disclosure-original source provision. Shams pins his argument entirely on the version of 31 U.S.C. § 3730(e)(4) in effect prior to Congress' amendment of that statute effective on March 23, 2010. Shams is correct that under that pre-2010 version of the § 3730(e)(4) —which is irrelevant to this case—a relator's

failure to satisfy the public disclosure-original source provision was a jurisdictional bar to maintaining an FCA action.

However, as explained above in Section I of this memorandum, the only false claims by Shams at issue herein are those submitted by Shams to Medicare subsequent to the filing date of Levine's original complaint, June 29, 2012. Thus, it is indisputable that it is the post-2010 version of 31 U.S.C. § 3730(e)(4) governs this action.

The timing is critical because—as this Court noted earlier this year—the 2010 amendment to §3730(e)(4) "removed the jurisdictional bar" that existed in the pre-amendment version of §3730(e)(4). *U.S.. ex rel. Aryai v. Skanska*, 09 CIV. 5456 (LGS), 2019 WL 1258938, at *3 (S.D.N.Y. Mar. 19, 2019) (citing *U.S. ex rel. Chorches v. Am. Med. Response, Inc.*, 865 F.3d 71, 80 (2017) (holding that "the public disclosure bar is no longer jurisdictional")) (*"Chorches"*). *See State Farm Fire and Cas. Co. v. U.S. ex rel. Rigsby*, 137 S. Ct. 436, 440 (2016).

Although neither this Court nor the Second Circuit Court of Appeals has addressed the issue, the five Circuit Courts of Appeals that have done so uniformly agree that, pursuant to the 2010 amendment, it is defendants—not relators—who now bear the burden of proving the relator relied on publicly disclosed information. Thus, the 2010 Amendment **eliminated the relator's burden of establishing jurisdiction**, *i.e.*, by proving she or he had **not relied** on "public disclosures." Instead, it is defendants who now "must first identify 'public documents that could plausibly contain allegations or transactions upon which the relator's action is based.'" *Little v. Shell Expl. & Prod. Co.*, 690 F.3d 282, 292 (5th Cir. 2012)(quoting *U.S. ex rel. Jamison v. McKesson Corp.*, 649 F.3d 322, 327 (5th Cir. 2011)). The First, Third, Eighth, and Eleventh Circuits agree.

Significantly, where, as here, defendants fail to carry their burden on the first, "public disclosure" prong of § 3730(e)(4)(A)'s "two-prong test," *U.S. ex rel. Kester v. Novartis Pharm. Corp., Med & Med GD,* 2015 WL 109934, at *7 (S.D.N.Y. Jan. 6, 2015)(per McMahon, C.J.), *see U.S. ex rel. JDJ & Associates LLP v. Natixis,* 15-CV-5427 (PKC), 2017 WL 4357797, at *5 (S.D.N.Y. Sept. 29, 2017), the relator has no need to prove, demonstrate, or establish, and the Court has no "need [to] consider whether the Relator was an 'original source'" of the publicly disclosed information. *Id.* at *15. *See U.S. v. Omnicare, Inc.,* 903 F.3d 78, 94 n.12 (3d Cir. 2018), *cert. denied sub nom*. *Pharmerica Corp. v. U.S. ex rel. Silver*, 18-1044, 2019 WL 4923459 (U.S. Oct. 7, 2019); *U.S. ex rel. Kraxberger v. Kansas City Power and Light Co.*, 756 F.3d 1075, 1082 (8th Cir. 2014).

Thus, post-FCA Amendment, the relator no longer is required "to prove a negative: that there are ***no*** public disclosures of allegations or transactions upon which his action is based." *McKesson*, 649 F.3d at 327 (emphasis in the original). *See U.S. ex rel. Moore & Co., P.A. v. Majestic Blue Fisheries, LLC*, 812 F.3d 294, 301 (3d Cir. 2016); ; *U.S. ex rel. Kraxberger v. Kansas City Power and Light Co.*, 756 F.3d 1075, 1082 (8th Cir. 2014).

Shams has not met **his** burden of showing the information on which Levine relies had been publicly disclosed information prior to the filing of his original complaint. Shams cites (at Memo., p. 13) **only four paragraphs and a footnote**—¶¶ 87, 89-91, and 128, and note 3—as the basis for his contention that Levine based the complaint on public disclosures. An examination reveals that none of those qualify as public disclosures within the meaning of the statute.

The first prong of the applicable version of § 3730(e)(4) states:

> The court shall dismiss an action or claim under this section, unless opposed by the Government, **if substantially the same allegations or transactions as alleged in the action or claim were publicly disclosed**—
>
> > (i) in a Federal criminal, civil, or administrative hearing in which the Government or its agent is a party;
> >
> > (ii) in a congressional, Government Accountability Office, or other Federal report, hearing, audit, or investigation; or
> >
> > (iii) from the news media … (emphasis supplied).

Thus, Shams bears the burden of showing that Levine's allegations in ¶¶ 87, 89-91, and 128, and note 3 "are substantially the same … as" allegations in a Federal hearing the Government was a party to, or in one of the enumerated types of reports, or in the news media.

We consider the complaint allegations cited by Shams and demonstrate that none qualify as being based on public disclosures within the meaning of this statutory provision.

Paragraph 87 alleges:

> In the case of [Patient] RG, Dr. Levine called and spoke to Dr. Shams to see if there was some particular reason the patient needed to be seen so soon after the successful declotting, which was entirely contrary to Dr. Levine's experience when performing access procedures, and in this case as it applies to a successful percutaneous thrombectomy. Additionally, the mere fact Dr. Shams and the Beth Israel Union Square Center took it upon themselves to schedule RG for a follow-up fistulagram was contrary to what he understood to be within the boundaries of good medical practice and Medicare regulations. Dr. Shams admitted to Dr. Levine that it was their routine **practice to schedule patients for a two week follow-up following angioplasty** associated with a percutaneous thrombectomy, **and that "everyone did it"** including American Access Care.

(Emphasis added). This paragraph describes Shams's first-hand admission to Levine that led Levine to believe that Shams routinely engaged in a practice of scheduling medically unnecessary follow-up procedures. Shams attempted to justify his practice by saying that "everyone did it." Levine's allegation in this paragraph clearly is not the same allegation or

transaction as was reported in a disqualifying source. So, Shams fails to carry his burden to show a public disclosure by invoking ¶ 87.

The next paragraph of the Amended Complaint listed by Shams, ¶ 89, states:

> Dr. Shams' implication that he dealt with Patient RG (and his other patients) in the same way as American Access Care is telling. In June 2015, the Department of Justice (DOJ) settled an FCA qui tam suit against American Access Care Miami LLC alleging that it engaged in the very same unnecessary and illegal practices as described herein (brought by a different relator).

This paragraph does refer to a Federal proceeding, but one brought against a different defendant by a different relator. Levine is not suing American Access Care, so it is clearly not the case that Levine's allegations are "the same allegations and transaction" that were at issue in that publicly disclosed lawsuit. Again, Shams fails to carry his burden.

Paragraph 90 refers to another first-hand admission by another physician to Levine in a direct conversation between the two with no argument by Shams that their conversation entered the public domain:

> Further, the then medical director of American Access Care, Dr. Greg Miller had related to Dr. Levine at a conference in San Francisco in October 2010 that he routinely performs angioplasties and inserts stents into cephalic vein arch stenoses. …

Shams clearly failed to satisfy his burden by citing this paragraph.

Fourth, Shams looks to ¶ 91:

> Thus, Dr. Shams' statement to justify his routine scheduling of Patient RG for follow-up medical appointments because "everyone did it" including American Access Care bolstered Dr. Levine's conclusion that Dr. Shams engaged in these unnecessary and illegal practices as a matter of course.

This paragraph describes Levine's reasoning process based upon his two direct conversations with Shams and Miller. Levine learned information in his private conversation with Miller that

led Levine reasonably to believe that American Access Care was performing unnecessary procedures (¶ 90), and that context—which was not publicly disclosed—led Levine to reach a similar conclusion about Shams' fraudulent practice when Shams admitted in what, again, was private exchange, that "everyone did it" including American Access Care (¶ 87). So, Shams does not satisfy his burden by pointing to ¶ 91.

Next, Shams cites to ¶ 128 where Levine pleaded as follows:

> On information and belief, at least 27% of the angioplasties Dr. Shams performed in 2012 were medically unnecessary. This percentage is based on an estimate by a medical expert in another matter involving similar fraud allegations that was settled by the Department of Justice. Thus, 112 of Dr. Sham's angioplasties in 2012 were unnecessary resulting in FCA damages of 112 times $224, which was the average reimbursement Medicare made to Dr. Shams for this procedure in 2012, or total single damages based on this procedure alone of at least $25,088.

The 27% figure for distinguishing medically unnecessary versus necessary procedures clearly is a placeholder for a percentage Levine intends to develop for purposes of his case from expert examination of medical records for Shams's patients. *See* ¶ 137 ("This is an estimate only, with the actual amount of damages to be determined by the jury at trial.) Levine included it merely to put Defendants on notice as to the rough order of magnitude of the damages that are at issue in the case.

The final instance of an allegation Shams argues was based on a public disclosures is footnote 3 (which appears on page 6). This is a footnote to ¶ 12 of the Amended Complaint, which merely notes that Levine was a contributor to the National Kidney Foundation's first Dialysis Outcomes Quality Initiative (NKF-DOQI) for Vascular Access as part of the description of Levine's qualifications and background. The footnote provides a link to the NKF-DOQI. Paragraph 12 clearly is not part of the substantive, fraudulent allegations or transactions alleged

in this case. So, this final instance by Shams of an alleged public disclosure falls just as do the others.

Therefore, Shams has failed to carry his burden of showing otherwise, and this Court should deny Shams's Rule 12(b)(1) motion.

IV. IF THE COURT CONSIDERS THE EXTRANEOUS MATERIAL SHAMS ATTACHES TO HIS MOTION TO DISMISS, THE COURT SHOULD CONVERT SHAMS'S MOTION TO A RULE 56 MOTION FOR SUMMARY JUDGMENT, AND DEFER A DECISION UNTIL SUCH TIME AS LEVINE HAS HAD ADEQUATE DISCOVERY

Shams's MTD is replete with references to the eight Exhibits attached to the Declaration of Stephen Wagner, one of his attorneys. *See* Shams's MTD at 2 n.1, 7 n.7, 9, 9 n.12, 10, 10 n.13, 10 n.14, 11, 18, 18 n.26, 18-19 n.27, and 19.

In ruling on a motion to dismiss, although this Court is "'not bound to accept as true a legal conclusion couched as a factual allegation,'" the Court "'must take all of the factual allegations in the complaint as true.'" *Wood v. Moss*, 572 U.S. 744, 755 (2014) (quoting *Ashcroft v. Iqbal,* 556 U.S. 662, 678 (2009)). As *Iqbal* explains, "[t]o survive a motion to dismiss," all that "a complaint must contain" is

> sufficient factual matter, accepted as true, to state a claim to relief that is plausible on its face. A claim as **facial plausibility** when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged. **The plausibility standard is not akin to a probability requirement**, but it asks for more than a sheer possibility that a defendant has acted unlawfully. Where a complaint pleads facts that are merely consistent with a defendant's liability, it stops short of the line between possibility and plausibility of entitlement to relief.

556 U.S. at 678 (emphasis added; internal citations and quotation marks omitted).

Shams contends Levine's Amended Complaint falls short of this standard—and thus that this Court must dismiss his complaint—not because Levine's claims are "**facially implausible**"

but because underlying factual allegations either are **factually improbable** because they are putatively 'contradicted by documents incorporated into the pleadings by reference'," which "need not be accepted as true,'" Shams's MTD at 15 (quoting *Secs. Investor Protection Corp. v. Bernard L. Madoff Inv. Secs. LLC*, 505 B.R. 135, 141 (S.D.N.Y. 2013)), or are **factually improbable** because they are contradicted by "'matters of which a court may take judicial notice,'" which include "'records and reports of administrative bodies,'" as well as "'documents "integral" to the complaint and relied upon in it, even if not attached or incorporated by reference [and] documents or information contained in defendant's motion papers if plaintiff has knowledge or possession of the material and relied on it in framing the complaint.'" Id. (citations omitted).

Shams's MTD is replete with references to the six Exhibits attached to the Declaration of Stephen Wagner, one of his attorneys. *See* Shams's MTD at 2 n.1, 7 n.7, 9, 9 n.12, 10, 10 n.13, 10 n.14, 11, 18, 18 n.26, 18-19 n.27, and 19. Shams asserts there are four reasons why

> [t]he Court can consider the CMS data, and CMS' commentary thereto (Wagner Decl. Exs. 4-8) …
>
> (i) the Amended Complaint incorporates such data by reference,
>
> (ii) the CMS data is "integral" to the Amended Complaint,
>
> (iii) Levine clearly relied on this CMS data in drafting the Amended Complaint, and
>
> (iv) the Court can take judicial notice of records and reports of CMS, a federal administrative body.

Shams's MTD at 18 n.26.

Shams's characterization of the eight exhibits attached to the Wagner Declaration as "the CMS data," "this CMS data," and "records and reports of CMS" is misleading and highly prejudicial. In fact, the exhibits supplied by Shams are nothing but a single newspaper's

ostensibly accurate interpretations of "CMS data," **and not** "CMS data," itself. For example, Exhibit 4 (Dkt. Nos. 182-184) purports to be a true and accurate print-out of an analysis of the "total Medicare payments" paid to Shams in 2012, an analysis made by a Wall Street Journal "project" titled *Medicare Unmasked: Behind the Numbers* and published by the Journal sometime in 2015. Significantly, the "project's" authors do not claim to reproduce CMS data; instead, they modestly say "[t]his project uses data made public by the Centers for Medicare and Medicaid Services," *i.e.,* CMS. Ex. 4 at 3. Exhibits 5, 6, and 7 are more of the same.[6]

These newspaper articles may contain admissible and reliable evidence but they certainly are not subject to judicial notice. The fact that these publications "**use**[] data made public by" CMS does not mean they ***are*** CMS data.

In this respect, Exhibits 4-7 should be disregarded as matters outside the pleadings, at least for the purposes of a Rule 12(b)(6) motion. Rule 12(d) provides, in full:

> If, on a motion under Rule 12(b)(6) or 12(c), matters outside the pleadings are presented to and not excluded by the court, the motion **must be treated as one for summary judgment** under Rule 56. All parties must be given a reasonable opportunity to present all the material that is pertinent to the motion.

(Emphasis added). Importantly, as the Court of Appeals stressed earlier this year:

> Rule 12(d), therefore, presents district courts with **only two options**: (1) "the court may **exclude the additional material** and decide the motion on the complaint alone" or (2) "it may **convert the motion to one for summary judgment** under Fed. R. Civ. P. 56 and afford all parties the opportunity to present supporting material."

[6] To be sure, Exhibit 8 was published by CMS, but it never references Shams and provides nothing more than a general "Methodological Overview" of "Medicare Fee-For-Service Provider Utilization & Payment Data Physician and Other Supplier Public Use File." Ex. 8 at 1.

Palin v. New York Times Co., 940 F.3d 804, 810–11 (2d Cir. 2019) (emphasis added; quoting Rule 12(d) and citing *Kopec v. Coughlin*, 922 F.2d 152, 154 (2d Cir. 1991) (quoting *Fonte v. Bd. of Managers of Continental Towers Condo*., 848 F.2d 24, 25 (2d Cir. 1988))).

Levine respectfully submits that, if this Court should consider the extraneous material attached to Shams's MTD, the Court should convert Shams's motion to dismiss "to one for summary judgment," and stay consideration of that Rule 56 motion until discovery has been completed and all parties have been "afford[ed] … the opportunity to present supporting material" gathered in discovery. Rule 12(d).

V. RELATOR'S AMENDED COMPLAINT STATES LEGALLY SUFFICIENT CAUSES OF ACTION AGAINST DRS. ROBERT, ALBERT, AND DANIEL, MATALON PURSUANT TO THE FALSE CLAIMS ACT, 31 U.S.C. § 3729, AND, THEREFORE, THE MATALONS' MTD SHOULD BE DENIED.

The Amended Complaint states legally sufficient claims against Dr. Robert Matalon, Dr. Albert Matalon, and Dr. Daniel Matalon for violations of the False Claims Act, 31 U.S.C. §3729, and satisfies the requirements of Rules 12(b)(6) and 9(b).

According to the Amended Complaint, Dr. Robert Matalon is a member of Nephrology Associates of Manhattan, and also owns and operates Lower Manhattan Dialysis Centers at 17th and 34th streets, Chinatown Dialysis Center, and River Renal Dialysis Center located at Bellevue Hospital, which is part of the New York City Health and Hospitals Corporation. All of these facilities are located in Manhattan, New York City, N.Y. (Amended Complaint, ¶ 22). Dr. Albert Matalon is Dr. Robert Matalon's son, is also a member of Nephrology Associates, and helps his father staff his dialysis clinics (Amended Complaint, ¶ 23.) Similarly, Dr. Daniel Matalon is the son of Dr. Robert Matalon, is a member of Nephrology Associates, and provides assistance to his father in staffing his dialysis clinics. (Amended Complaint, ¶ 24.)

Levine personally observed during his time working for Robert Matalon and with the Albert Matalon and Daniel Matalon the following particulars regarding the Matalons' causal role in the fraudulent scheme by Shams:

The Matalon Defendants regularly referred their patients, and the patients of other treating nephrologists receiving dialysis at their facilities, to Shams vascular access center, knowing that he engaged in the practice of self-referrals, and therefore knowing that he was generating unnecessary and unreasonable claims to the Medicare and Medicaid Programs. (Amended Complaint, ¶ 113.)

Levine observed that Dr. Robert Matalon went along and collaborated with the interventional radiologists and the vascular access centers to which he referred patients, including Dr. Shams and Beth Israel, by allowing, or at least not stopping, the patients from going for appointments to these centers on a regular basis to have their accesses evaluated without proper referrals made by him or his staff for specific clinical indications. Amended Complaint, ¶ 115.)

Significantly, Levine observed that whenever Dr. Robert Matalon learned some patients receiving dialysis in his units were going for access procedures to qualified interventional radiologists other than Shams, he instructed the Chinatown Dialysis Unit support staff—whose responsibility it was to schedule such appointments and arrange the necessary van transport (to be discussed in detail below)—to intensify their efforts to direct as many patients as possible to Shams and the Beth Israel Union Square Center. (Amended Complaint, ¶ 115.)

Multiple times Levine was informed by patients he cared for while employed by Dr. Robert Matalon that they had been instructed and scheduled to return for follow-up appointments

for access evaluations even though neither Levine, nor any of the other healthcare professionals in the dialysis units, initiated the referrals. (Amended Complaint, ¶ 85.)

Levine reasoned that it was virtually inevitable that the Matalons would learn that their patients were undergoing unnecessary procedures in view of the fact that he himself (Levine) readily understood this based on his own personal interactions with patients of the Matalons. According to the Amended Complaint, Levine learned that his (and the Matalons') Patient RG had been scheduled by Beth Israel for a follow-up appointment, notwithstanding that the percutaneous thrombectomy performed at Beth Israel Union Square Radiology Center had been successful, which meant no follow-up appointment and procedure was medically necessary (Amended Complaint, ¶ 86.) When Levine queried Shams about this highly unusual and medically (and legally) problematic practice, Shams admitted that it was a routine practice for Beth Israel to schedule patients for follow-up appointments and procedures. (Amended Complaint, ¶¶ 87-88.)

Similarly, Levine treated Patient JO. JO experienced access thrombosis, and also was referred to Beth Israel for declotting. This procedure was successful. Yet, Dr. Levine learned that JO also had been scheduled for a two week follow-up visit to Beth Israel's access clinic. (See Amended Complaint, ¶ 92.)

Levine treated RG and JO while they were the Matalons' patients or patients of the Matalon-owned and controlled dialysis facilities. Another example is the Matalons' Patient CB, who was a medical professional. CB told Levine that he/she was undergoing angiograms and angioplasties about every three months. Levine asked CB why this was the case. CB answered he/she could not provide a specific indication for these repeated procedures, and suggested it might be an example of a medical "New York hustle." He/she also stated he/she was dealing

with so many other personal and medical issues that he/she didn't even want to think that perhaps he/she was allowing himself/herself to undergo medically unnecessary procedures. (Amended Complaint, ¶ 119.)

It is on the basis of these kinds of personal, particularized occurrences that Levine reasonably inferred that patients invariably provide feedback to their treating physicians regarding the examinations and procedures specialists perform on the patients as a result of referrals by the primary to the specialists, (Amended Complaint, ¶ 115), and, therefore, that the Matalons would know that Shams was performing unnecessary services not supported by clinical indications specific to the patients involved, and that the Matalons knowingly condoned this fraudulent activity by Shams. (Amended Complaint, ¶ 74.)

Additionally, Levine alleges in the Amended Complaint that there is usually physical evidence of the procedure, such as a suture or bandage that is readily observable to the treating nephrologist. Furthermore, it is standard medical procedure for a specialist who performs a procedure on a patient to send "procedure notes" to the patient's primary physician, which are then added to the patient's chart. (Amended Complaint, ¶ 115.)

Moreover, Levine knew from his personal medical practice that the vascular access centers performing excessive and unnecessary angiograms, angioplasties, and other interventional procedures would have sent notes documenting the performed procedures to the Matalons for patients under their care, as well as for patients sent from their dialysis units to the access centers. Those procedures would have been added to these patients' charts. Those charts would have routinely and regularly have been reviewed by Albert Matalon and Daniel Matalon, and by the staff of their and their father's dialysis units, in the normal course of further treating the patients, and that review would have informed the Matalons of the practice of the vascular

access centers, including those of Shams and Beth Israel, of engaging in self-referrals. (Amended Complaint, ¶ 116.)

Moreover, the Matalons' patients and those being treated in their dialysis units would have routinely and regularly have discussed the fact that they were being self-referred by the access center. (Amended Complaint, ¶ 117.)

Many dialysis patients are poor and lack transportation. If they are too ill to travel by public transportation, the Government reimburses the cost of a van to transport them to medical providers. Many of the patients in the Matalons' dialysis units legitimately required such transportation support to travel to and from the dialysis units. In addition, other medical appointments that the patients in the Matalons' units required, including appointments with access centers, were arranged by the support staff employed by the Matalons. When the Matalons' employees scheduled such appointments, including ones at access centers, they also would arrange the necessary van transport. (Amended Complaint, ¶ 120.)

By ordering and/or authorizing his staff to schedule access-related appointments with specific providers such as Shams, and because the van-dependent patients could only travel to the destinations that the staff arranged, Dr. Robert Matalon, with the full knowledge of Dr. Daniel and Dr. Albert Matalon, used the Government's transportation largesse to "steer" patients from his dialysis facilities to the access centers they knew were engaged in self-referrals. This system of arranging transport to the access centers would have also placed the Matalons on notice of the excessive frequency with which their patients were returning unnecessarily to the access centers. (Amended Complaint, ¶ 120.)

At some point when Levine was working with Robert Matalon, the latter told Levine that he was considering opening his own access center. Levine pointed out to him that, in estimating

the profitability of an access center, he would have to discount the portion of revenues that many such centers received from illegal self-referrals; in other words, he could not rely on the revenues of such facilities as Dr. McGuckin's to predict the potential profitability of any access center he (Dr. Robert Matalon) might open because of the improper activities engaged in by the former. Dr. Robert Matalon responded to Levine's admonition with words to the effect of "a number of them [vascular access facilities] are shady." This conversation shows that Dr. Robert Matalon was on notice of the rampant nature of the self-referral practices by many vascular access centers, including those of Shams at Beth Israel. (Amended Complaint, ¶ 122.)

Levine observed Dr. Robert Matalon boasting that all decisions for referral to vascular access centers must meet a "What's in it for me?" test. (Amended Complaint, ¶ 121.)

Yet, the Matalons continued to feed a steady stream of patients to these fraudulent vascular access centers performing unnecessary procedures and non-covered vascular access monitoring and surveillance, and did so over many years, thereby knowingly causing the false and fraudulent claims submitted to the Government by the latter. (Amended Complaint, ¶ 123.) In so doing, they caused Shams' to submit false claims within the meaning of the FCA.

It is well-accepted "False Claims Act liability attaches not only to the actual maker of the false statement, but also to 'any person who knowingly assisted in causing the government to pay claims which were grounded in fraud, without regard to whether that person had direct contractual relations with the government' or only had contact with the government through an 'intermediary.'" *U.S. v. Raymond & Whitcomb Co.*, 53 F. Supp. 2d 436, 445 (S.D.N.Y. 1999) (quoting *U.S. ex rel. Marcus v. Hess*, 317 U.S. 537, 544-45 (1943*),* superseded in part on other grounds as noted in *Schindler Elevator Corp. v. U.S. ex rel. Kirk*, 563 U.S. 401, 412 (2011)). The FCA also "'gives the United States a cause of action against a subcontractor who causes a prime

contractor to submit a false claim.'" *Id.* (quoting *U.S. v. Bornstein*, 423 U.S. 303, 309 (1976) (holding a defendant liable for causing another contractor to submit false claims to the Government)).

Indeed, in *Hess,* the Supreme Court interpreted the "causing to be presented language" of an earlier version of the FCA to "reach any person who knowingly assisted in causing the government to pay claims which were grounded in fraud, without regard to whether that person had direct contractual relations with the government." *Hess*, 317 U.S. at 544-45. Thus,

> [t]he Supreme Court has long held that a non-submitting entity may be liable under the FCA for knowingly causing a submitting entity to submit a false or fraudulent claim, and it has not conditioned this liability on whether the submitting entity knew or should have known about a non-submitting entity's unlawful conduct.

U.S. ex rel. Hutcheson v. Blackstone Med., Inc., 647 F.3d 377, 390 (1st Cir. 2011).

As a court explained in *U.S. ex rel. Long v. SCS Bus. & Tech. Inst*., 999 F. Supp. 78, 90–91 (D.D.C. 1998) ("*Long*"), *rev'd on other grounds*, 173 F.3d 870 (D.C. Cir. 1999), "[a]ccording to the Senate Report, this knowing standard does not require either actual knowledge of the fraud or specific intent to commit the fraud." *Id.,* 999 F. Supp. 2d at 90 (citing S.Rep. No. 99–345, at 7, 1986 U.S. Code Cong. & Admin. News 5266).

> In defining knowingly, **Congress attempted "to reach what has become known as the 'ostrich' type situation where an individual has 'buried his head in the sand' and failed to make simple inquiries which would alert him that false claims are being submitted**." Congress adopted "the concept that individuals and contractors receiving public funds have some duty to make a limited inquiry so as to be reasonably certain they are entitled to the money they seek."

United States v. Bourseau, 531 F.3d 1159, 1168 (9th Cir. 2008) (emphasis added; quoting S. Rep. No. 99–345 at 21, 20).

> Indeed, Congress clarified the "knowing" standard in 1986 to emphasize that the government need not prove that the defendant had actual knowledge or a specific intent to submit a false claim, reasoning that this high standard was "inappropriate in a civil remedy" and "prohibit[ed] the filing of many civil actions to recover taxpayer funds lost to fraud."

United States ex rel. Bledsoe v. Community Health Sys., Inc., 342 F.3d 634, 642 n.6 (6th Cir. 2003) (quoting S. Rep. No. 99–345, at 7). *See United States ex rel. Phalp v. Lincare Holdings, Inc.*, 857 F.3d 1148, 1155–56 (11th Cir. 2017). *See also Universal Health Servs., Inc. v. United States ex rel. Escobar*, —— U.S. ——, 136 S.Ct. 1989, 2000, 195 L.Ed.2d 348 (2016).

Long involved alleged false claims for Federal education funds relating to proprietary schools operated by a company in New York. The relator sued the State of New York, alleging the State, which played an oversight role, was liable for causing the false claims because it failed to halt the fraud once it learned of it. The court explained:

> The question here is whether New York knowingly "caused" false claims to be presented when it allegedly did not prevent the claims from being presented. . . . The Court finds . . . New York's arguments unpersuasive. First, the issue is not whether the New York defendants violated the FCA by not closing down the SCS schools once New York learned of the alleged fraud. The issue here is whether New York's alleged failure to act was a course of conduct that allowed fraudulent claims to be presented to the federal government. Long has alleged, with the requisite specificity, that New York officials allowed false claims to be presented to the federal government over a number of years, and even after it knew that false claims were being made.

999 F. Supp. at 91. The court allowed the suit to go forward against New York.

In *United States v. President & Fellows of Harvard Coll.*, 323 F. Supp. 2d 151, 187 (D. Mass. 2004) (favorably cited in *United States ex rel. Schagrin v. LDR Indus., LLC*, 2018 WL 6064699 (N.D. Ill. 2018)) at *17, the court wrote:

> Where a defendant has an ongoing business relationship with a repeated false claimant, and the defendant knows of the false

> claims, yet does not cease doing business with the claimant or disclose the false claims to the United States, the defendant's ostrich-like behavior itself becomes a course of conduct that allowed fraudulent claims to be presented to the government.

This is precisely what the Matalons did with respect to Shams's fraudulent course of conduct and false claims, and, they therefore are liable for causing Shams's false claims.

In addition to causing the false claims submitted by Shams, the Matalons directly submitted their own false claims for capitation payments.

As alleged in the Amended Complaint, nephrologists such as the Matalons are compensated by Medicare for providing services relating to surveilling the vascular accesses of their patients including dialysis patients. These payments are based on the frequency with which the treating physician sees a given patient each month. (Amended Complaint, ¶ 54.)

Because a patient's dialysis facility and treating nephrologist are paid by Medicare and Medicaid to monitor each patient's hemodialysis vascular access, other medical professionals should not take that responsibility upon themselves. Doing so would not only be duplicative, it would encourage nephrologists and dialysis facilities to reduce the treatment they provide to patients even though they are expected to perform the service and are paid for doing so under the Medicare and Medicaid programs. (Amended Complaint, ¶ 55.)

Furthermore, because the nephrologist and the dialysis facility are in the best position to determine if there is evidence to suggest additional evaluation of and interventions upon the patient's access are medically reasonable and necessary in order to maintain optimal, complication free access function, the dialysis facility and the nephrologist, not third-party treating physicians or access centers, are the individuals whom Medicare and Medicaid expect to make the decision to refer patients to specialists for additional evaluations and interventions such as diagnostic angiograms, angioplasty, and, when necessary, surgical revision, prior to the

onset of critical access dysfunction, thrombosis, or other associated complications. (Amended Complaint, ¶ 56.)

Because the Matalons continued to feed a steady stream of patients to Shams's Beth Israel vascular fraudulent access centers performing unnecessary procedures and non-covered vascular access monitoring and surveillance, and did so over many years (Amended Complaint, ¶ 123), the Matalons "farmed out" the management and observation of patients' access to the access clinics operated by Shams and Beth Israel. If they had been performing access surveillance as required by Medicare and Medicaid regulations, they would not have permitted their patients to submit to fistulagrams and other procedures at the access centers without the proper clinical indications. In knowingly so doing, they vitiated the medical necessity of their own claims for capitated payments, and therefore rendered those claims false within the meaning of the FCA. (Amended Complaint, ¶ 125.)

Levine estimate that, during the years 2012 through 2017, Albert and Daniel Matalon submitted claims for, and were paid a total of approximately $670,000 in capitation payments. (Amended Complaint, ¶ 126.) These claims were submitted on Forms 1500 and 1450. (Amended Complaint, ¶ 51.

Accordingly, the Matalon Defendants violated the FCA by causing the false and fraudulent claims submitted by Shams, and the Matalons submitted and caused to be submitted their own false and fraudulent claims for capitation payments paid by Medicare.

CONCLUSION

For the foregoing reasons, the MTDs of all Defendants should be denied.

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on the 25th day of November 2019, I electronically served the foregoing on all counsel of record.

By: s/ John A. Kolar